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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of) Examiner: Kathryn Odland
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Harry J. Buncke) Group Art Unit: 3743
)
Serial No.09/596,806) File No.: 540P
)
Filed: June 19, 2000)
)
For: SURGICAL CLIP APPLIER) Tiburon, California
WITH REMOTE OPERATION)

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

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ON October 1, 2004
THOMAS M. FREIBURGER, Reg. No. 27,063
SIGNED [Signature]
DATE 10-1-04

Dear Sir:

APPLICANT'S REPLY BRIEF

This is in reply to the Examiner's Answer which was mailed
September 23, 2004.

This brief will comment on and correct some misconceptions
and unsupported and confusing arguments made by the examiner in
her brief on appeal.

At page two, under "5. Summary of Invention", the
examiner's statement regarding new matter is mistaken. Claim 1,
near the end of the penultimate paragraph, has this
characterization regarding the flexible device as being
sufficiently flexible as to avoid movement of the clip applier's

tip when the hand operable actuator is moved to apply the force. The examiner had no objection when this wording was added to claim 1 during prosecution of the application, and there was no basis for any such objection. The entire patent application is based on the flexible device having such flexibility. In the summary, page 5, lines 1-6, it is stated that the device allows the clip applier to be actuated without applying force directly to the hand-held clip applier, thus to isolate any vibration or unsteady movement from reaching the clip applier tip. Obviously the flexible line has to be sufficiently flimsy to prevent transfer of actuating motion to the hand-held device itself. Further, an example of the flexible actuator is given as a cable release device, (page 6, line 4); and this may be the type of cable release device used with a camera (page 11, lines 6-7). Such camera cable release devices are extremely well known, and are flexible and flimsy so as to accomplish the exact same purpose as in the present invention: to avoid hand motion, jerking or vibration at the camera itself, at the instant when the shutter is opened. Thus there is no question that the subject words are adequately supported in the specification, the words in the claim simply paraphrasing the entire tenor of the specification and simply repeating the goal of "isolating any vibration or unsteady movement from the clip applier tip" (p. 5, l. 5-6).

Regarding page 4 of the examiner's argument, the applicant respectfully submits that these arguments are unsupported and confusing and assume facts which are not true.

The applicant stands by the statement quoted at the top of page 4 of the examiner's argument. The Swiggett reference certainly does relate to a different purpose, and does not seek to avoid movement induced by the surgeon's hand, translating through the length of the device to the applier tip. The reference's purpose is to grip and steer the Swiggett device using its intended handle, and to steer the remote tip through the provision of a stiff but bendable shaft 14 which retains the bend that is put into it by the surgeon.¹ Manifestly, the surgeon could not do this if the shaft 14 were sufficiently flexible to avoid picking up any movement of the operator's hand at the remote end, i.e. between the intended handle 12, 30 and the end 20 in Swiggett. Note that Swiggett defines his actuator as his handle Section (col. 2, l. 15-16).

The examiner, however, seeks to find a common goal between the applicant's invention and Swiggett, in the concept of "remote actuation". This is an anomaly, because the remote actuation provided by and intended by Swiggett is a different type of remote actuation from what is defined in the present application

¹See Swiggett, col. 1, l. 48-59 and col. 2, l. 20-22: "The shaft is longitudinally flexible in any direction, and once bent into a given shape, will retain that shape."

and in the present claims. The examiner reminds us of a second benefit of the applicant's invention, in serving the problem of narrow access in a wound or body cavity. That second purpose of this invention is served by removing the need to squeeze the handle 10a of the applicant's device, which might not be possible in a narrow cavity. Compare the prior VCS clip applier 10 shown in Figures 1 and 2, wherein the actuator wings 18 had to be squeezed by the surgeon at the instant of applying a clip.

The examiner argues that a purpose of the present invention, in the examiner's words, "is for remote operation in deep inaccessible areas, as discussed in the Summary of the Invention", and that Swiggett also has such a goal. But what does this prove? The claims still require that a flexible force applying device be sufficiently flexible to avoid movement of the tip when the remote actuator is engaged and moved to apply the force to dispense a clip. Such a flexible force applying device is not shown or suggested in either Swiggett or in the acknowledged prior art, the VCS clip applier. The examiner argues the purpose of both devices is remote actuation, but to follow the examiner's analogy one would have to hold the applicant's device by the end of the flexible cable (e.g. 60 in Fig. 5) as a handle and where the force is applied, and that is impossible because of the highly flexible nature of the cable or force applying device pursuant to the purpose of the invention.

Near the bottom of page 4, the examiner says, "Further, the modification would necessarily yield isolation movement via a surgeon's hand." The meaning of this statement is not apparent. The "modification" presumably refers to the examiner's proposed modification of the prior VCS applier pursuant to the teachings of Swiggett. But the point the examiner seeks to make with the rest of the sentence is difficult to determine ("yield isolation movement via the surgeon's hand").

This is not a case where any motivation existed in the references, or was inherent in the art, to make the modification proposed by the examiner. First, the examiner's proposed modification would not produce the claimed device, primarily because the Swiggett extension device is stiff but bendable so as to assume a configuration selected by the surgeon. Secondly, Swiggett's teaching of a device which acts as a probe to enter a lumen of a human organ (such as the colon), with a bendable but stiff probe piece, certainly does not provide motivation even to invent a device that isolates an applicator tip from motion induced by the hand (or foot) at the end of a remote actuator cable, let alone to seek to import any features of Swiggett into the prior art VCS applier. There is absolutely no motivation in the art to attempt such a combination - this is not an In re Wright situation where a specific modification could have been made for a different reason from that of the applicant. There is

no different reason.

At page 5 of the examiner's argument, near the bottom, she seeks to discount the arguments regarding "sufficiently flexible" as irrelevant. Far from irrelevant, this expression is in the claims, and the cable's flexibility is defined throughout the specification as meaning flexible to the extent that no movement from the actuating hand is induced into the handle. There was no issue during prosecution regarding the term "sufficiently flexible" as supported in the specification, and none exists now.

Beginning at page 6, line 3 of the examiner's argument, she takes issue with the applicant's statement that to hold the applicator end of Swiggett's device in the hand of the surgeon would be contrary to the purpose of Swiggett. This indeed is contrary to the purpose of Swiggett because Swiggett teaches a device for entering a lumen of an organ in the human body, where "remote actuation" means going up a narrow lumen to a site that cannot be reached with the hand. Thus, it is contrary to Swiggett's purpose to have the hand of the surgeon gripping that remote end, which might be deep inside the patient's colon. In support of the examiner's argument she says "it is a well known goal in the medical art to have remote actuation for numerous purposes", but she provides no reference beyond Swiggett, and this statement should be disregarded.

Also, the examiner again says that Swiggett and the present

device have the same "purpose of remote application" (p. 6, l. 9), and that this somehow provides motivation. Again, the applicant's remote actuation is different from the reference's remote application, the reference's purpose being to extend into an unreachable lumen within an organ of the human body and the applicant's purpose being to operate a clip applier generally of the type in the prior art but with remote actuation via a flexible cable so as to avoid shaking the clip applier tip at the instant of applying the force. These are not common or similar goals.

This is a §103 rejection, not a §102 rejection; thus goals, purposes and teachings of the reference are important.

Concerning the method claim rejections, the applicant stands on its prior statements. As noted above, the examiner's proposed combination would not even yield the claimed device. Even if it did produce that claimed device, there is no teaching of the method of claims 9 et seq. anywhere in the art. There must be some teaching in the art that would produce or suggest the method recited in the claims. Claim 9 requires that the engaging of the remote actuator not be performed by the hand that holds the handle of the clip applier. The acknowledged prior art teaches the opposite of this; Swiggett also teaches the opposite (to the extent Swiggett's teaching is relevant at all), since the reference teaches squeezing the handle 12, 30 of his device to

effect clip application at a working, clip applying end that extends from a stiff but bendable shaft from the handle. Any vibration or muscular jerking motion of the hand holding Swiggett's handle would actually be multiplied by the long extension shaft 14 so that an even greater vibration or movement is projected at Swiggett's tip 20, frustrating the purposes of this invention and contradicting the method stated in claims 9-11. Note that claims 10 and 11 recite actuation by a different person; and actuation using a foot pedal, features the examiner did not feel any need to address apparently because of her belief that the method is inherently obvious simply because of her position that the device is obvious.

The applicant believes the rejections are manifestly in error and unsupported and should be overturned.

Respectfully,

A handwritten signature in black ink, appearing to read 'Th. M. Freiburger', with a large, stylized flourish extending from the bottom right.

Date: October 1, 2004

Thomas M. Freiburger
Reg. No. 27,063
P.O. Box 1026
Tiburon, California 94920
415-435-0240